

REMARKS

Applicant respectfully requests reconsideration. Claims 1-4, 6-8, 10-23 and 25 were previously pending in this application. Claims 1, 2, 4, 18, 21 and 22 have been amended. Support for the amendment of claim 1 can be found in the specification as filed in paragraphs [0021], [0041] and [0066]. No new matter has been added.

Interview Request

Applicant respectfully requests a telephone interview with the Examiner in the event that this amendment does not place all claims in condition for allowance.

Rejections Under 35 U.S.C. § 112

The Examiner rejected claims 2, 4, 18, 21 and 22 under 35 U.S.C. § 112, second paragraph, as indefinite.

Applicant has amended claims 2, 4, 18, 21 and 22 to remove recitations of narrower ranges. Accordingly, withdrawal of the rejection of claims 2, 4, 18, 21 and 22 under 35 U.S.C. §112 is respectfully requested.

Rejections Under 35 U.S.C. § 103

I. The Examiner rejected claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1). Applicant traverses the rejection and respectfully requests reconsideration.

On page 4 on the Office Action, the Examiner stated:

"Webster et al. teach a *cannabinoid extraction method* comprising harvesting Cannabis composed of seed and chaff; separating the chaff from the seed; extracting the chaff with a solvent, thereby producing an extract; passing the extract, if desired, over a chromatographic column arranged to fractionate Δ^9 -THC [*sic*; Δ^9 -THC], thereby producing a whole hemp extract without Δ^9 -THC [*sic*; Δ^9 -THC]." (Emphasis added).

Applicant respectfully disagrees. In fact, the passage referred to by the Examiner (column 2, lines 5 to 23) does not describe a "cannabinoid extraction method", but rather a "method of preparing a Cannabis extract" (column 2, lines 6 to 7). There is no suggestion that the "Cannabis extract" according to this first aspect of Webster is a cannabinoid, pure or otherwise. Indeed, as the Examiner has recognized, this process produces a "whole hemp extract without the Δ^9 -THC" (column 2, lines 17 to 18).

This process does not provide the features of the process described in claim 1, since it does not result in the production of purified CBD, but rather a "whole hemp extract". Furthermore, there is no mention of the use of a non-polar solvent which is a C5-C12 straight chain or branched chain alkane or a carbonate ester of a C1-C12 alcohol for the *selective isolation* of cannabidiol from plant material.

The process described in the first aspect of Webster and exemplified in Example I would not result in selective isolation of substantially pure cannabidiol as required by claim 1 and the Examiner concedes on page 4 of the Office Action that it is a "whole hemp extract". The disclosure of Webster also confirms that fractionation techniques such as HPLC should be used to isolate individual components of the whole hemp extract, in particular cannabinoid and cannflavin compounds (column 5, lines 62 to 67):

"Individual components or analytes may be isolated from the [extract of Example I] by subjecting the extract to high pressure liquid chromatography (HPLC) using, for example, a reversed phase C₁₈ column and a mobile phase made up of for example acetonitrile and water and methanol and water for the isolation of cannabinoid and cannflavin compounds."

Therefore, the Applicant submits that the process described in the first aspect of Webster does not provide the features of the current claims.

The Examiner continues, stating that "the cannabinoid may be selected from cannabidiol" and referencing column 2, lines 56 to 63 of Webster. However, this passage in Webster relates not to the *first* aspect described in Webster (a method of preparing a Cannabis extract, which as described above does not provide the features of Applicant's claims) but to the *fourth* aspect, i.e. "a method of extracting a cannabinoid, cannflavin or essential oil from Cannabis". (see Webster, col. 2, lines 40-42) It is important to note that this fourth aspect is described as having the following steps:

"harvesting Cannabis composed of seed and chaff;
separating the chaff from the seed;
extracting the chaff with a solvent, thereby producing an extract;
*passing the extract over a chromatographic column arranged to
fractionate the cannabinoid, cannflavin or essential oil of interest out of the
extract; and*
collecting the fractions containing the cannabinoid, cannflavin or
essential oil of interest from the column, producing a purified cannabinoid,
cannflavin or essential oil."
(col. 2, lines 43-52; Emphasis added)

Here, the words "if desired" are absent, indicating that a fractionation step is an *essential feature* of this method. Clearly, the Examiner's statement on page 9 of the current Office Action, that "the use of a chromatographic column is optional in the process of Webster" only applies to the first aspect of Webster (a method of preparing a Cannabis extract) and not to the fourth aspect (a method of extracting a cannabinoid, cannflavin or essential oil from Cannabis).

The Examiner also argues that claim 8 of Webster teaches obtaining purified cannabidiol. Claim 8 of Webster incorporates all the features of claim 1, which clearly includes the use of a chromatographic column. There is no indication in claim 1 or claim 8 that the chromatographic column is optional. Thus, the Examiner's two adjacent statements, "the use of a chromatographic column is optional in the process of Webster" and "Webster does teach obtaining purified cannabidiol" in fact apply to different aspects of the invention of Webster.

Example I of Webster includes a filtration step, however this is irrelevant since the process used in Example I is that of Webster's first aspect, i.e. a method of preparing a Cannabis extract. By the Examiner's own admission on page 4 of the Office Action, this extract is a "whole hemp extract" and is not a method that selectively isolates substantially purified cannabidiol as is claimed by Applicant.

Thus, Webster does not disclose a process that is capable of producing a purified cannabidiol from Cannabis plant material *without* the use of a fractionation step. Webster contains no teaching that would enable the skilled person to produce purified cannabidiol based on solvent extraction alone. Furthermore, absolutely no teaching is given regarding *selective* isolation of CBD from plant material as is claimed in amended claim 1; the amendments further clarify the selective nature of the current method. The teachings of the Adams and Schmidt references do nothing to remedy this basic deficiency.

Furthermore, claim 1 has been amended to specify that the optional secondary extraction step in (a) is a solvent extraction. Claim 1 as amended therefore excludes fractionation of the extract obtained in step (a), since the wording of (b) demands that the extract obtained in (a) is dissolved in a C5-C12 straight chain or branched chain alkane or a carbonate ester of a C1-C12 alcohol to form a solution. Similarly, step (c) requires that *this* solution is filtered, excluding an intermediary fractionation step.

Thus neither the Webster reference alone nor the combination of the Webster, Adams and Schmidt references provide the elements of the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

2. The Examiner rejected claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. §103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US

6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669).

The Examiner argues that the skilled person would replace the supercritical CO₂ extraction step in Whittle with the hydrocarbon-based extraction of Webster. However, the replacement of CO₂ with a hydrocarbon solvent does not result in the method of claim 1, since neither Whittle nor Webster disclose the use of a C5-C12 straight chain or branched chain alkane or a carbonate ester of a C1-C12 alcohol for the selective isolation of cannabidiol. The use of such a solvent after the initial extraction is required by step (b) of claim 1. In effect, the current method is a two stage process. There is no teaching in Webster or Whittle that indicates that a C5-C12 straight chain or branched chain alkane or a carbonate ester of a C1-C12 alcohol may be used to *selectively isolate* cannabidiol from an initial crude or whole extract of cannabis plant material.

The relative ease with which a particular solvent could be obtained does not change the fact that neither process produces pure cannabidiol.

The Examiner comments on page 10 of the Office Action that "Webster teaches that other solvents may be used as modifiers *in combination* with the supercritical fluid for targeted extraction of specific compounds" (emphasis added). According to Webster, supercritical CO₂ extraction methods may involve the use of additional solvents, but these are applied to the target material at the same time as the supercritical fluid. The teaching of Webster, as highlighted by the Examiner, confirms this. By contrast, the current claims do not encompass a method in which the solvent specified in step (b) is to be used at the same time as any solvent extraction used in step (a).

The final paragraph of page 10 of the current Office Action reiterates the Examiner's argument that the use of fractionation is merely optional in Webster. For the reasons outlined above in response to the rejection based on Webster as the primary reference, Applicant submits that the Examiner's conclusion on the teaching of Webster is incorrect. In order to produce purified cannabinoids, the use of fractionation is essential when following the teaching of

Webster. Instant claim 1 as amended relies on a combination of solvent extraction steps, not fractionation as taught in Webster.

There is no suggestion in any of the cited prior art documents that it is possible to obtain purified cannabidiol using solvent extraction steps alone, and even if there were there is no teaching regarding the choice of solvents. Thus, the method described by current claim 1 is not disclosed in the cited prior art documents either alone or in combination.

Schmidt also teaches that fractionation is required in order to isolate pure CBD or THC.

The combination of references thus contains no teaching that would enable the skilled person to produce purified cannabidiol based on solvent extraction alone. Furthermore, absolutely no teaching is given regarding *selective* isolation of CBD from plant material as is claimed in amended claim 1. Neither Schmidt nor Adams provide the features of the currently claimed method that are lacking in Webster and Whittle.

Thus the combination of the Whittle, Webster, Adams and Schmidt references do not provide the elements of the claimed invention and therefore do not render the claimed invention obvious.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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